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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,697	04/05/2002	Akane Takemura	011633	3246
23850 7590 08/12/2008 KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. Suite 400 WASHINGTON, DC 20005				
EXAMINER				
PORTER, RACHEL L				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/926,697

Applicant(s)

TAKEMURA ET AL.

Examiner

RACHEL L. PORTER

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-52 is/are pending in the application.
4a) Of the above claim(s) 23-46 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 47-52 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment and election filed 4/25/08.

Claims 23-52 are pending. Claims 23-46 have been withdrawn from consideration.

Claims 47-52 are presented for examination.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 47-52 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the statute, the claimed invention must fall into one of the four recognized statutory classes of invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter.

In the instant case, the preamble of claim 47 recites a system. However, it is unclear whether the recited components (i.e. parts) are hardware or software components. Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart

functionality either to the data as so structured, or to the computer. Such "descriptive material" is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).) (See MPEP 2105).

Furthermore, claims 47-52 merely recites non-functional descriptive material, as no recitation of a processor, memory, executable code being embodied on any medium or data structure is provided. Simply stated, the "tools", "section", and "parts" as recited in claims 47-52 fail to have a tangible result.

In light of the above, it is respectfully submitted that the claimed invention of exemplary claim 47, is not does not useful, tangible, and concrete result, and thus fails to recite the practical application of an abstract idea to satisfy the requirements of 35 U.S.C. 101.

Also, a similar analysis may be applied to claim 48-52 with the recitation of risk improvement tools.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 47-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As per claim 47-50 and 52, it is unclear as to which a statutory class of invention the applicant intends to claim. While the preamble recites a "system," the body of the claim recites a combination of possible components (parts) and risk improvement tools (i.e. software with no interrelationship to a computer to have its functionality realized. Similarly, it is unclear which statutory class of invention claim 51, which recites a "risk set" including a "table" and one of a plurality of items (e.g. software) is directed to.

Furthermore, the use of the "and/or" phrase in claims 51-52 renders claims vague and indefinite because it is unclear which features are required as a part of the claimed invention. In other words, it is not clear whether one or both of the listed features are required for the claimed invention. For the purpose of applying art, the Examiner will interpret "and/or" as "or" and apply art according.

NOTE: In light of the extensive 112 2nd problems, the examiner is interpreting the claims and applying prior art as best possible using these interpretations. These interpretations of claim language are for examination purposes only.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 47-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Dewey et al (US 5,084,819).

[claim 47] Dewey discloses a disease risk improvement sheet comprising a risk estimation processing part and a risk avoidance measure presentation processing part, wherein said risk estimation processing part has:

- a data gathering part provided with an examination item display section that displays a plurality of risk factors and means for examining the presence or absence or current state of the risk factors, and an answers section corresponding to the examination item display section; (Tables 1, 4—solicits users for questions and answers are shown)
- a judgement criteria part provided with a risk value judgement criteria section that stipulates an unequivocal correlation between the answers and preset risk values; (Tables 2-3- assigns weights to answers and determines a score)
- a risk judgement part provided with a judgement section for recording the risk values for the risk factors converted from the answers based on the risk value judgement criteria section and calculating an overall risk value by arithmetic processing; and (Table 3)
- an overall risk display part provided with an overall risk judgement criteria section that unequivocally stipulates an overall risk allocated to one of a plurality of

preset levels from the overall risk value. (Table 5 –summarizes weighted answers, gives risks and scores).

It is noted that Dewey is not specifically directed toward oral disease. However, these limitations are nonfunctional description material and are not functionally involved or required for table. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability. See *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994).

[Claim 48] Dewey discloses a disease risk improvement sheet recited in claim 47, wherein said overall risk display art is provided with:

- an overall risk judgement criteria section that unequivocally stipulates an overall risk allocated to one of a plurality of preset levels from the overall risk value, (Tables 2-3)
- an overall risk display section that displays an overall risk showing a risk level of an examinee, and (Tables 4-5)
- an explanation section that explains the risk level. (Tables 4-5)

[Claim 49] Dewey discloses the disease risk improvement sheet recited in claim 47, wherein said risk avoidance measure presentation processing part is provided with a risk avoidance measure display part and an improvement possibility display part. (Table 5: quit smoking, lower blood pressure)

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[Claim 50] Dewey discloses the disease risk improvement sheet recited in claim 47, wherein said risk avoidance measure display part is provided with:

- a risk avoidance measure presentation criteria section in which are shown the necessity of re-examination and the time of re-examination (recall judgement), (Table 4: follow-up on treatment regarding hypertension)
- a guidance display section in which are displayed guidance contents for guiding lifestyle habits so as to reduce the risk, and (Tables 4-5: quitting smoking reduces your risks...continue to keep up the habit change)
- a means display section in which are displayed means necessary for carrying out the risk improvement in accordance with a guidance of said guidance display section. (Tables 4-5: quitting smoking reduces your risks...continue to keep up the habit change)

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dewey in view of Connelly (US 5,738,113)

[Claim 51] Dewey discloses an oral disease risk improvement sheet recited in any one of claims 47 to 50, but does not expressly disclose providing a risk improvement

tools including guidance tools comprising any one of videos, CDs, cassette tapes, panels, books, computer software containing guidance on improving eating habits and brushing guidance used for the purpose of teaching knowledge and increasing awareness with regard to oral hygiene, diseases, or products for the oral cavity comprising any one of the mouthwashes, sprays, foams, gels, tablets, chews, capsules, gum, foods, toothbrushes, interdental brushes, dental floss, and irrigators.

Connelly discloses providing risk improvement tools to patients including products for the oral cavity comprising any one of the mouthwashes, sprays, foams, gels, tablets, chews, capsules, gum, foods, toothbrushes, interdental brushes, dental floss, and irrigators. (col. 10, lines 1-60, figure 10). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Dewey with the teaching of Connelly to include products to prevent or reduce disease risk. As suggested by Connelly, one would have been motivated to include these feature to provide cost-effective, inexpensive interventions which require minimal dental infrastructure (col. 2, lines 25-29)

[Claim 52] The limitations of claim 52 are addressed by the rejections of claims 47-51.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure Steinberg et al (US 6,025,326). disclose methods for treatments of oral diseases.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, (Christopher) Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/R. L. P./

Examiner, Art Unit 3626

/C Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626